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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Inga Reynisdottir

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EXAMINER

SWITZER, JULIET CAROLINE

ART UNIT

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1634

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/533,365	<b>Applicant(s)</b> REYNISDOTTIR ET AL.	
	<b>Examiner</b> Juliet C. Switzer	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21,23,24,27-42 and 44-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-21,23,24,27-42 and 44-50 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Sequence Rules***

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

\*\*\*There are sequences recited in the drawings that are not identified with proper sequence identifiers.

\*\*\*There is no paper copy of the sequence listing in the file.

In response to this correspondence, applicant is required to comply with the sequence rules, 37 CFR 1.821 - 1.825. In order to comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825), Applicant must submit, as necessary, a new CRF and paper copy of the Sequence Listing containing these sequences, in addition to the previously listed sequences, an amendment directing the entry of the Sequence Listing into the specification, an amendment directing the insertion of the SEQ ID NOs into the appropriate pages of the specification and a letter stating that the content of the paper and computer readable copies are the same.

Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g).

### ***Election/Restrictions***

2. The previously set forth restriction requirement is withdrawn and a new requirement is set forth in this correspondence. The grouping of claims has been changed upon further

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consideration of the claim set. Further, the election of species has been clarified with regard to group 1 in particular. If applicant desires to maintain the election of Group 1, marker DG5S881 that was as set forth in the paper dated Feb 29, 2008, applicant should reiterate as much in response to this restriction requirement.

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claims 1, 3, 6, 27-30, 36-42, 44-48, drawn to a method of diagnosing a susceptibility to type II diabetes comprising detecting a polymorphism in a SLIT-3 nucleic acid and methods for detecting SLIT-3 nucleic acids.

Group 2, claim 2, drawn to a method of diagnosing a susceptibility to type II diabetes comprising detecting an alteration in the expression or composition of a polypeptide encoded by SLIT-3 nucleic acid in a test sample.

Group 3, claims 4-5 and 7-9, and 31-35, in their entirety, and claims 19-21 as they refer to SLIT-3 nucleic acids, drawn to isolated nucleic acids, vectors, host cells and methods of producing polypeptides.

Group 4, claim 10, drawn to a method of assaying for the presence of a polypeptide via contact with an antibody.

Group 5, claims 11 and 13-14, drawn to a method of identifying an agent that alters SLIT-3 nucleic acid expression.

Group 6, claim 12, 15, and 16, an agent that alters expression of a SLIT-3 nucleic acid.

Group 7, claim 17, a method of altering SLIT-3 expression.

Group 8, claim 18, a method for identifying a polypeptide which interacts with a SLIT-3 polypeptide comprising a polymorphism.

Group 9, claims 19-21 in part, a therapeutic agent.

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Group 10, claims 23-24, a method of treating a disease or condition.

Group 11, claim 49-50, use of a therapeutic agent to manufacture a medicament.

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

**Group 1 includes methods for detection of a variety of particular nucleic acids.**

Claims 3 and 45 recite detecting the presence of “at least one” or “one or more” of the polymorphisms indicated in Figure 11, which includes 117 SNP and microsatellites identified as polymorphic within SLIT3. Examples of combinations of “at least one” or “one or more” are the haplotypes given in Tables 2 and 5.

Claims 6, 30, 36, 38, refer to using or detecting a nucleic acid molecule that is selected from those nucleic acid sequences shown in Figure 10. Figure 10 provides the nucleic acid sequences of SNPs identified across SLIT3.

Claims 39 and 44 refer to determining the presence or absence of a haplotype shown in Table 2 or Table 5. These haplotypes are combinations of polymorphisms from Figure 11.

Each combination of polymorphisms in Figure 11 is considered a different species.

Each method for detecting a unique nucleic acid or combination of nucleic acids is considered a different species. **Applicant should select a single combination of at least one polymorphism from those recited in the claims.** Applicant should identify the elected polymorphism (or polymorphisms) by the name used to identify it in the specification and also identify the SEQ ID NO which disclose the context of the polymorphism(s) in the specification. A combination of “at least one” is considered to encompass any group of one, two, three, or more up to all of the possible markers.

Claims which refer to specific polymorphisms or nucleic acid sequences will be examined only insofar as they read on detection of the elected combination of sequences. For example, if applicant maintains the previous election of marker DG5S881 as the

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single combination of “one or more” (this being a combination of one), claims 1, 3, 27, 28, 29, 45, 46, 47, and 48 and will remain under examination, but claims 6, 30, 36, 38, 39, 40, 41, 42, and 44 will be withdrawn from prosecution because these do not read on this marker whose sequence is given in Figure 12 or because these require analysis of a different group of markers.

**Group 3, group 4, group 5, and group 8**, the species include each of the 120 nucleotide sequences recited in Figure 10.

**Group 6** the species include (i) each of the 120 nucleotide sequences recited in Figure 10 and (ii) each of the 9 different agents listed in the claims.

**Group 7**, the species are each of the 9 different agents listed in the claims.

**Group 9**, the species are each of the 22 different agents listed in the claims.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

All of the claims recite species in the alternative.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

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The groups listed as groups 1-11 are not joined by a special technical feature because there is no feature that is common to all of the groups, required by the independent claim in each group. Group 1 is drawn to a method of diagnosing a susceptibility to type II diabetes, and does not recite or require specifically the nucleic acids of group 3, for example. Groups 2-13 are each drawn to products and methods which are not joined to group 1 as they have unique goals, method steps and uses. The products are not joined to one another as they are separate in chemical structure and make up, for example the products of group 3 are drawn to nucleic acids while the products of group 6 include a wide variety of molecules directed towards the alteration of expression of a nucleic acid. Thus, groups 1-11 are not joined by a special technical feature in view of the prior art.

The species of group 1 are all different polymorphisms within nucleic acid sequences which are not joined by a special technical feature as they are all variations in sequences, and are different in structure, function and effect on the nucleic acid within which they are embedded. Further, the specification itself admits that many of these polymorphisms are within the prior art as it provides the "Public alias" for these polymorphisms, which is a code by which they are identified within public databases. Therefore the species of group 1 are not joined by a special technical feature. The haplotypes of the species of group 1 each have unique structures and functional implications

The additional recited species are all distinct chemical molecules that are not joined by a common structure or feature. The additional species are all molecules having sequences that are different from one another, joined only by the fact that they are nucleic acid molecules or are all molecules which are not related in structure. .

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

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claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.



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7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday, Tuesday, or Wednesday, from 9:00 AM until 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached by calling (571) 272-0735.

The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of

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the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Juliet C. Switzer/  
Primary Examiner  
Art Unit 1634

May 17, 2008